

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: ELDRIDGE, Rosa L., et al.)

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Filed: Herewith)

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For: Intravascular Infusion)

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Site Anti-Tamper Guard)

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Having Means For)

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Site Inspection)

**STATEMENT BY ROSA LEE ELDRIDGE IN
SUPPORT OF PETITION TO MAKE SPECIAL**

The treatment of HIV/AIDS, cancer, and similar life-threatening diseases requires utilization of a multitude of intravascular infusion sites in the patient's extremities and the patient's chest and neck. For young patients under the age of 17, and for patients over the age of 45 undergoing treatment for HIV/AIDS and/or cancer, each preferred site and each additional viable infusion site must be protected from damage due to the limited number of viable infusion sites available for these young and/or older patients. Damage to these infusion sites typically occur due to patient tampering with the catheters and associated tubing because of the patient's disorientation or youth. Tampering with the catheter or associated tubing leads rapidly to leakage by infiltration into the surrounding dermal tissue of the treatment fluids. The treatment fluids include highly reactive vasoconstricting agents and/or caustic medicines utilized for treatment of HIV/AIDS and/or cancer. Infiltration of the highly reactive treatment fluids rapidly leads to the extreme stage of tissue disruption identified as extravasation, with rapid degradation of the surrounding perivascular tissue, subcutaneous tissue, and dermal tissue in as little as six hours or within approximately twenty-four hours from initiation of infiltration of the treatment fluids. The resulting degradation of the infusion site due to extravasation leads to a vein or artery that is not viable as a candidate for an infusion site for continued treatment for HIV/AIDS and/or cancer.

An explanation of the severity of the problem imposed by extravasation in cancer patients is provided in Cancer Medicine, No. 5, by Holland and Frei (2000) (An approved publication of the American Cancer Society®). "Cancer patients are inherently at high risk of extravasation for several reasons. These patients often require multiple venipuncture sites and have thin and fragile veins, concomitant peripheral vascular disease, and malnutrition. In addition, the number of optimal intravenous sites may be reduced due to previous chemotherapy, cutaneous radiation therapy changes, and lymphedema secondary to surgery." (Narin Apisarnthanarax, MD, and Madeleine. Duvic, MD, authors of Article No. 144, Cancer Medicine, Ed. 5, by Holland & Frei (2000, published by B.C. Decker, Inc., London)).

The number of diagnoses of young and aged patients suffering from HIV/AIDS and/or cancer (Category 2 neoplasms), and undergoing treatment is significant and is increasing at an alarming rate. One source of information is provided by the Agency for Healthcare Research and Quality (AHRQ) (see <http://www.ahrq.gov/>, and <http://hcup.ahrq.gov/HCUPnet.asp>).

In response to an AHRQ Nationwide Inpatient Sample (NIS) for 2001, approximately 986 hospitals in 33 states responded (approximately 20% of all U.S. hospitals. The NIS identified reported patient diagnoses for 2001 of:

2,333 of HIV/AIDS cases for ages <1 to 17;
143,619 of HIV/AIDS cases for ages 18 to 44;
78,200 of HIV/AIDS cases for ages 45 to 85+;
162,920 of Category 2 neoplasms for ages <1 to 17;
848,153 of Category 2 neoplasms for ages 18 to 44; and
6,087,159 of Category 2 neoplasms for ages 45 to 85+.

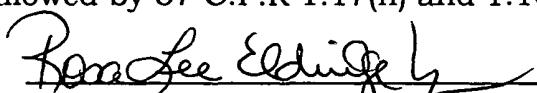
Accidental extravasation of treatment fluids has been estimated to occur in approximately 6% of the patients receiving intravenous chemotherapy treatment. The total aggregate costs for treatment of neoplasms in the U.S. have been estimated at \$45,022,090,409 for 2001. Aggregate costs for treatment of HIV/AIDS cases in the U.S. were not available.

The invention referenced hereinabove provides a tamper resistant guard for covering an intravascular infusion site to protect the site from tampering by patients including young or aged patients who may be disoriented and/or heavily sedated. The tamper resistant guard further provides for rapid visual inspection by a medical practitioner of the infusion site for indications of infiltration and extravasation of caustic treatment fluids, which lead to atrophy of dermal tissues proximal to the infusion site. Frequent inspections of each infusion site and rapid correction of potential leakage of caustic treatment fluids is a necessity if the patient's limited number of infusion sites are to be protected for the continuing use of each infusion site for long-term treatment for HIV/AIDS, and/or cancer, and similar life-threatening diseases.

The tamper resistant guard allows a medical practitioner to timely identify and correct a dislodged catheter, and/or change the infusion site utilized for injection of treatment fluids for treatment of HIV/AIDS, cancer, and similar life-threatening diseases, in order to prevent loss of an infusion site.

I hereby request that the above-referenced invention disclosed in a patent application filed concurrently with this Statement, be accorded special examination status based upon the subject invention providing for improved treatment of HIV/AIDS or cancer, as allowed by 37 C.F.R 1.17(h) and 1.102(d).

Dated: 7-18-03


Rosa Lee Eldridge, L.P.N.
RR 1, Box 358, Rose Hill, VA 24281